DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Changes in Enforcement of FDA's Requirements on Reprocessing of Single-Use Devices

(You are encouraged to copy and distribute this information)

September 25, 2001

Dear Hospital Administrator and Hospital Risk Manager:

The purpose of this letter is to alert you to a change in FDA's policy on the reuse of single-use devices (SUDs) that will affect all hospital SUD reprocessors. Specifically, FDA is extending the deadline for active enforcement to August 14, 2002, for the following postmarket requirements: medical device reporting, tracking, corrections and removals, quality system, and labeling.

FDA's schedule for enforcement of other requirements remains unchanged. As previously announced, FDA plans to begin inspecting hospital SUD reprocessors shortly. FDA will immediately enforce the requirements for establishment registration and device listing. FDA is actively phasing-in enforcement of its premarket requirements (as described below).

Change in enforcement approach to hospital SUD reprocessors

Beginning this fall, FDA intends to inspect hospital SUD reprocessors. These inspections will cover all three classes (I, II, and III) of medical devices. The change in FDA's reuse policy concerns the focus and possible outcomes of these inspections. The focus will be to assess hospitals' compliance with the Agency's postmarket regulatory requirements. However, the Agency does not intend to take enforcement actions against hospitals if they are found not to be in compliance with these requirements. Rather, FDA plans to spend the next year educating hospitals on complying with the postmarket requirements. This policy will remain in effect until August 14, 2002, provided that the hospitals are taking steps to correct the violations noted during the inspection and that the violations do not pose a serious public health risk. This revised policy does not apply to third party reprocessors.

FDA will still enforce requirements for registration and device listing

As stated in the *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (SUD enforcement guidance),[1] which was published by FDA on August 14, 2000, the Agency will actively enforce registration and device listing

[1] A copy of the SUD enforcement guidance is available on FDA's Internet site: www.fda.gov/cdrh/reuse/index.shtml or by calling CDRH Facts on Demand at 1-800-899-0381 or by calling 301-827-0111, specify number 1168 when prompted for the document shelf number.

requirements for all hospital SUD reprocessors. These requirements remain unchanged and will be **actively enforced** by FDA immediately.

Examples of completed registration and device listing forms

To facilitate hospital SUD reprocessor registration and device listing, we have provided an example of a completed FDA Form 2891 "Initial Registration of Device Establishment" (see Attachment A). Hospital reprocessors that are registering for the first time with FDA must use this form. Also enclosed is an example of a completed FDA Form 2892 "Device Listing" (see Attachment B). This form must be used to identify the SUDs that a hospital reprocesses.

Additional details regarding registration and listing are available in "CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA-2891, 2891a, and 2892." The guidance is available from FDA's Internet site www.fda.gov/cdrh/dsma/rlman.html. You may also obtain a copy by calling Facts-on-Demand at 1-800-899-0381 or 301-827-0111 (please specify number 012 when prompted for the document number).

Where to obtain registration and listing forms

Registration forms are available from FDA's Internet site www.fda.gov/cdrh/reglistpage.html. Because the device listing forms are uniquely numbered, they are not available from our Internet site.

You may obtain registration and listing forms from the Division of Small Manufacturers, International, and Consumer Assistance by e-mailing dsma@cdrh.fda.gov or by faxing 301-443-8818. Please provide your name, address, telephone number, and the quantity of forms you need. (Note that a separate FDA Form 2892 form must be submitted for each category or type of device that a hospital reprocesses.)

Completing and submitting registration and listing forms

FDA has created a new identification code to identify establishments that reprocess medical devices. The new code is "*MB*". When completing the establishment registration form, select the code "MB" under section "*9. Establishment Type*" and write in this code under section "*12. Establishment Name and Address*" on the device listing form. Please note that completed registration and listing forms must be submitted together. If you submit the forms separately, they will be returned to you.

FDA will still enforce requirements for premarket submissions

There are no changes to the premarket submission requirements[2] or to FDA's timetable for enforcing these requirements. Hospital SUD reprocessors must submit to FDA, a PMA or a 510(k) for any class III, non-exempt class II, or non-exempt class I device that they reprocess. As described in the SUD enforcement guidance, FDA's deadline for enforcement of PMA or 510(k) submission requirements for class III devices was February 14, 2001. The enforcement date for the submission of a 510(k) for a non-exempt class II SUD was August 14, 2001. The enforcement date for the submission of a 510(k) for a non-exempt class I SUD is February 14, 2002. (See the SUD enforcement guidance for additional details.) FDA intends to **actively enforce** the premarket submission requirements.

Recommendations

If your hospital is reprocessing SUDs, we strongly encourage you to immediately register your facility and to list the devices that you are reprocessing with FDA, if you have not already done so. Failure to comply with this requirement may cause your devices to be violative under the Federal Food, Drug and Cosmetic Act.[3]

We also encourage you to explore our Internet site for information and guidance on the SUD reuse issue (www.fda.gov/cdrh/reuse). For additional information, you may consult with the Division of Small Manufacturers, International, and Consumer Assistance by calling 1-800-638-2041 or e-mailing DSMA@CDRH.fda.gov.

Sincerely yours,

/s/

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health

Attachments (2)

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[2] The premarket requirements include the submission of a premarket approval application (PMA) or a premarket notification (510(k)) to FDA. The type of submission depends on the *Code of Federal Regulations* classification for the device.

[3] For additional information about types of FDA enforcement actions the Agency may take against non-compliant hospital SUD reprocessors, see the letter that FDA sent to all US hospitals on April 23, 2001. A copy of this letter is available on FDA's Internet site www.fda.gov/cdrh/reuse/042301_reuse.html.

Attachment A: Sample of a Completed Initial Registration Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: December 31, 2001

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. **REGISTRATION NO.** *(Leave Blank)*

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME			3. RECORD DATE (Mo.) (Day) (Yr.)	
ABC Hospital			*08 | 14 | 2001*	
4. NUMBER AND STREET	**5. CITY AND FOREIGN STATE**		**6. STATE**	**7.ZIP CODE**
9876 Jones Drive	*Randalstown*		*V | A*	*98765*
8. FOREIGN COUNTRY	**9. ESTABLISHMENT TYPE** ***(See Instructions Booklet)***		**10. PREPRODUCTION REGISTRATION**	
	E M R S T X ID MB		• **YES** ☑ **NO**	
	| | | | | | | X | | |			

SECTION B

11. OWNER/OPERATOR BUSINESS NAME			12. OWNER/OPERATOR I.D.	
ABC Medical Center of the Greater Metro Area			*(Leave Blank)*	
13. NUMBER AND STREET	**14. CITY AND FOREIGN STATE**		**15. STATE**	**16.ZIPCODE**
1234 Corporate Drive	*Bethesda*		*V | A*	*12345*
17. FOREIGN COUNTRY	**18. TELEPHONE NUMBER-IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT** ***(Area Code) (Number & Extension)***			
	301- 555-7777			

SECTION C

19. OFFICIAL CORRESPONDENT			20. REGISTRATION NUMBER	
Mrs. Dorothy Doe			*(LEAVE BLANK)*	
21. BUSINESS NAME				
ABC Medical Center of the Greater Metro Area				
22. NUMBER AND STREET	**23. CITY**		**24. STATE**	**25. ZIP CODE**
1234 Corporate Drive	*Bethesda*		*V | A*	*12345*
26. TELEPHONE NUMBER ***(Area Code) (Number and Extension)***		**27. FAX NUMBER** ***(Area Code) (Number)***		
301-555-7777		*301-555-8888*		

SECTION D

28. OTHER BUSINESS TRADING NAMES

(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name).

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1	*ABC Urgent Care*	SO4	
SO2	*ABC Surgical Outpatient Center*	SO5	
SO3		SO6	

SECTION E

29.SIGNATURE OF OFFICIAL CORRESPONDENT	30.TITLE
	Vice President, Hospital Administration

FORM FDA 2891 (8/00) **PREVIOUS EDITIONS ARE OBSOLETE** **EF**

Attachment B: Sample of a Completed Device Listing Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Form Approved: OMB No. 0910-0387.
Expiration Date: December 31, 2001

Complete and Return to: Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Boulevard
Rockville, MD 20850-4015

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER

C_____

(each form pre-numbered)

2. REASON FOR SUBMISSION

☑ New Listing
ÿ Update to Device Already Listed
ÿ Delete Listing

3. REPORT DATE

MO.	DAY	YR.
08	*14*	*2001*

4. OWNER/OPERATOR ID NUMBER

(Leave blank unless an ID number has been previously assigned to your owner/operator)

5. OWNER/OPERATOR NAME

ABC Medical Center of the Greater Metro Area

6. ADDRESS ***(Check*** ☑ *if same as submitted on FDA Form 2891)*

a. NUMBER and STREET

1234 Corporate Drive

b. CITY, STATE, ZIP CODE

Bethesda, Virginia 12345

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME

CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS & OPERATIVE

8. CLASSIFICATION NUMBER

LOX

9. PROPRIETARY NAME ***(Brand Name)***

Multiple

10. COMMON OR USUAL NAME

PTCA Balloon Catheter

11. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS

a. NAME	B. REGISTRATION NUMBER
Not applicable	*Not applicable*

12.

ESTABLISHMENT NAME AND ADDRESS
(Identification of Sites Where Listed Device is Produced)

REGISTRATION NO. TYPE (Name, Street Number, City, State or County, ZIP or Postal Code)	M	R	S	T	X	MB	ESTABLISHMENT	
A *(Reprocessors should check or write-in "M B")*								
ABC Hospital, 9876 Jones Drive, Randalstown,VA 98765						X		
B								
C								
D								

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Boulevard
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address,

13.SIGNATURE

14.TYPED OR PRINTED NAME

FORM FDA 2892 (1/99) PREVIOUS EDITIONS ARE OBSOLETE. EF